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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,539	04/05/2001	Howard Preissman	PX-02-2	9912

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EXAMINER	
MILLER, CHERYL L	
ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
09/18/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/828,539	PREISSMAN, HOWARD	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-44,46-53,55,56,58-63,65-70,72 and 73* is/are pending in the application.

4a) Of the above claim(s) *33-39 and 46-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-44, 55-56, 58-63, 65-70, and 72-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/10/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 40-44, 54-56, 58-70 and 72-73 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40, 44, 55-56, 58-59, 61-63, 65-66, 68-70, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Ersek et al. (US 5,258,028, cited previously).

Referring to claim 62, Ersek discloses an injectable composition (see fig.3, 4; col.2, lines 12-21; col.9, lines 21-25) comprising a flowable matrix (physiologic vehicle 31+some particles 30 considered flowable matrix) comprising PMMA (particles 30 may be made of PMMA, col.6, lines 50-54; thus the flowable matrix comprises PMMA) and radiopaque tracer particles (particles 30 may be coated with radiopaque coating; disclosed to be radiopaque, col.3, lines 15-19; col.10, lines 22-27) having a size of between about 350 microns and 2200 microns (col.2, lines 35-39), and wherein the particles are individually visible during implantation (inherently Ersek's particles are individually visible, since they are the same size as the applicant's particles, therefore, would have to be just as visible as the applicant's particles). Since the particles 30 may be made of PMMA and have a radiopaque coating, the matrix (30+31) comprises PMMA and radiopaque particles. Also, a handful of the particles 30 may be considered the PMMA of

the flowable matrix and a handful of the particles 30 may be considered the radiopaque particles in the flowable matrix.

Referring to claims 65 and 73, Ersek discloses the radiopaque particles to comprise barium compounds (col.10, lines 22-28).

Referring to claims 68-70, Ersek discloses the radiopaque particles to be sized between about 570u and 2200u, or between about 450u and 1600u and 570 and 1150 (all ranges fall within Ersek's disclosed range of between about 30u and 3000u; col. 2, lines 35-39).

Referring to claims 40, 44, 54-56, 58-59, 61, and 63:

It is recognized by the examiner that a board decision was made for claims 40-44 (see board decision August 10, 2005), similar subject matter which is claimed in claim 63, and the other claims listed are from which they depend, the decision which reversed the examiner on a 102 rejection over Ersek (US 5,258,028). *The reverse was cited to be improper not because of the size assessment, but instead the rationale cited, relating to obviousness instead of anticipation* "*if* Ersek were *to choose* 350um..". However, it is noted that this reference is now being applied to the claims in a different light/perspective and rationale, thus is considered a new rejection, relying on anticipation and not obviousness, see below.

Because the current rejection of the above claims is related to the board decision made on August 10, 2005, the examiner would like to respond on one comment made in the decision. The board cited col.3, lines 45-49 to indicate the need of Ersek to have a uniform particle size. However this is not what is recited at all. Ersek recites, "While in *most situations* the particles are of *random size* and configuration, but within the constraints of the size indicated, it is generally desirable that the particles be of generally uniform *configuration*". That is, Ersek

disclosed uniform *configuration*, not size. Further Ersek discloses a random size is preferred in *most situations*. Ersek further discloses that it is preferred to have a range of varied particle sizes, smaller and larger than the target size (col.5, line 64-col.6 line 2), further emphasizing the need from a varied sized composition.

Ersek discloses an injectable composition (see fig.3, 4; col.2, lines 12-21; col.9, lines 21-25) comprising a flowable matrix (physiologic vehicle 31 + particles 30; col.2, lines 47-52) comprising PMMA (particles 30 of matrix are disclosed to be PMMA, col.6, lines 51-55) and radiopaque tracer particles (particles 30 disclosed to be radiopaque, have radiopaque coating, col.3, lines 15-19; col.10, lines 22-27) wherein the particles are individually visible during implantation (inherently Ersek's particles are individually visible, since they are the same size as the applicant's particles, therefore, would have to be just as visible as the applicant's particles) and contrast particles that enhance the visibility of the matrix. Ersek discloses a particle range of 30-3000um. The applicant has claimed two different particle ranges, 350u-2200u and 120u-350u, which overlap at 350um. Both claimed particle ranges (along with applicant's overlap size 350um) fall within Ersek's disclosed particle range. Because Ersek's particle range of 30um-3000um includes 350um, 350um is anticipated by Ersek. Further, Ersek discloses that within any target particle size, there will be a percent of larger particles and a percent of smaller particles (see col.5, line 64-col.6, line 2), thus inherently 2 ranges at least are present (larger and smaller as disclosed by Ersek). Since the particles 30 may be made of PMMA and have a radiopaque coating, the matrix (30+31) comprises PMMA and radiopaque particles. Also, a handful of the particles 30 may be considered the PMMA of the flowable matrix and a handful of the particles 30 may be considered the radiopaque particles in the flowable matrix.

The above claims are considered by the examiner to be anticipated by Ersek.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

In the alternative to the above rejection, claims 40-44, 54-56, 58-61, 63, 66, 67, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek et al. (US 5,258,028, cited previously). Referring to claims 40 and 63, Ersek discloses an injectable composition (see fig.3, 4; col.2, lines 12-21; col.9, lines 21-25) comprising a flowable matrix (physiologic vehicle 31+particles 30) comprising PMMA (particles of the matrix disclosed to be PMMA col.6, lines 51-55) and radiopaque tracer particles (particles 30 disclosed to be coated radiopaque, col.3, lines 15-19; col.10, lines 22-27) wherein the particles are individually visible during implantation (inherently Ersek's particles are individually visible, since they are the same size as the applicant's particles, therefore, would have to be just as visible as the applicant's particles) and contrast particles that enhance the visibility of the matrix. Ersek discloses a particle range of 30-3000um. The applicant has claimed two different particle ranges, 350u-2200u and 120u-350u. Both claimed particle ranges fall within Ersek's disclosed particle range. It is also noted that applicant's two particle ranges overlap at 350u, which also falls within Ersek's disclosed particle range. Although Ersek has disclosed a wide particle range, *including* 350um (applicants particle overlap), and further discloses that in any target particle size, some larger and smaller will be present, col.5, line 64-col.6, line 2, Ersek does not specifically disclose the particle size 350

(which would include both ranges of applicants particles) or two different ranges of particles within Ersek's range to be present. It would have been obvious to one having ordinary skill in the art at the time the invention was made, for Ersek to have a particle size of 350um (especially since this size falls within Ersek's disclosed range of 30-3000um) or two different particle sizes within Ersek's disclosed range (30-3000um), since wherein the general conditions of a claim have been disclosed in the prior art (size range of 30-3000) it is not inventive to discover the optimum or workable ranges by routine experimentation (350um or two sizes or two particles of different sizes within 30-3000um). *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Since the particles 30 may be made of PMMA and have a radiopaque coating, the matrix (30+31) comprises PMMA and radiopaque particles. Also, a handful of the particles 30 may be considered the PMMA of the flowable matrix and a handful of the particles 30 may be considered the radiopaque particles in the flowable matrix.

Referring to claims 60, 67, and 72, Ersek discloses a composition of a matrix (vehicle) and particles, however is silent to mention the percent weight of the particles within the matrix. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the percent weight 1 or 10 percent, since wherein the general conditions of a claim have been disclosed in the prior art (particle concentrated in a matrix) it is not inventive to discover the optimum or workable ranges by routine experimentation (1 or 10 percent weight particles within matrix). *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 40-44, 55-56, 58-59, 62-63, 65-66, 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dowd et al. (US 5,507,813) in view of Fox (US 4,500,658). Dowd discloses an injectable implant comprising a flowable matrix (fillers, bonding agents, col.4, lines

1-5) and radiopaque particles (bone particles considered "equivalent materials", col.3, lines 12-22, bone which is radiopaque) having the size claimed (col.3, lines 1-10). Dowd discloses the flowable matrix to be an acrylic resin, however does not specifically disclose PMMA. Fox teaches or shows as evidence, PMMA is a very common acrylic resin used in bone repair. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dowd's composition with acrylic resin and radiopaque particles, with Fox's teaching of a particular common acrylic resin to be PMMA, to have a PMMA/radiopaque composition.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER